04-10-06

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant :	Peter Krulevitch, *et al.*	Docket No. :	IL-10580
Serial No. :	10/032,257	Art Unit :	1744
Filed :	12/21/2001	Examiner :	William H. Beissner
For :	MICROFABRICATED INSTRUMENT FOR TISSUE BIOPSY AND GENETIC ANALYSIS		

TRANSMITTAL OF APPELLANT'S BRIEF (PATENT APPLICATION - 37 CFR § 1.192)

Transmitted herewith is the **APPELLANT'S BRIEF** in this application with respect to the Notice of Appeal filed on March 22, 2006.

The item(s) checked below are appropriate:

1. **STATUS OF APPLICANT**
   This application is on behalf of
   - ☐ other than a small entity.
   - ■ a small entity.
     A verified statement
     - ☐ is attached
     - ■ already filed.

2. **FEE FOR FILING APPEAL BRIEF**
   Pursuant to 37 CFR 1.17(e) the fee for filing the Appeal Brief is:
   - ■ small entity $250.00
   - ☐ other than a small entity $500.00

Appeal Brief fee due **$250.00**

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on April 6, 2006

Kathy Raymond

3. **EXTENSION OF TIME**

☐ Applicant petitions for an extension of time under 37 CFR 1.136

Calculation of extension fee (37 CFR 1.17(a)-(d)):

	Total months requested	Fee for other than small entity	Fee for small entity
☐	one month	$120.00	$60.00
☐	two month	$450.00	$225.00
☐	three month	$1,020.00	$510.00
☐	four month	$1,590.00	$795.00
☐	five month	$2,160.00	$1,080.00
		Fee	**$000.00**

4. **FEE PAYMENT**

■ Charge Account No. 12-0695 in the amount of **$250.00**.

■ **Charge Account No. 12-0695 for any additional extension and/or fee required or credit for any excess fee paid.**

Eddie E. Scott
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Date: April 5, 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Peter Krulevitch, et al. **Attorney Docket No.:** IL-10580
Serial No.: 10/032,257 **Group Art Unit:** 1744
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Commissioner for Patents
Alexandria, VA 22313-1450

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Kathy Raymond
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Honorable Commissioner for Patents
Alexandria, VA 22313-1450

Attention: Board of Patent Appeals and Interferences

Dear Sir:

APPELLANT'S BRIEF (37 C.F.R. § 1.192)

This brief is submitted in support of appellant's notice of appeal from the decision of the Examiner, mailed March 6, 2006 finally rejecting claims 1-5 and 16-19 of the subject application.

Appellant's notice of appeal was mailed March 22, 2006.

One copy of the brief is being transmitted per 37 C.F.R. § 41.37.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest is:

The Regents of the University of California and the United States of America as represented by the United States Department of Energy (DOE) by virtue of an assignment by the inventor as duly recorded in the Assignment Branch of the U.S. Patent and Trademark Office.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

III. STATUS OF CLAIMS

The application as originally filed contained claims 1-19.

The status of all the claims in the proceeding (*e.g.*, rejected, allowed or confirmed, withdrawn, objected to, canceled) is:

claims 1-5 and 16-19 are rejected, and

claims 6-15 are cancelled.

The claims on appeal are claims 1-5 and 16-19.

Claims 1-5 and 16-19 on appeal are reproduced in the Appendix.

IV. STATUS OF AMENDMENTS

There have been no amendments filed subsequent to the Final Rejection mailed March 6, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Appellants are providing a concise explanation of the subject matter defined in each of the independent claims involved in the appeal, which refer to the specification by page and line number, and to the drawing, if any, by reference characters. There are two (2) independent claims involved in the appeal. Appellants' two independent claims involved in the appeal are claims 1 and 16. Appellant's two independent claims 1 and 16 on appeal are "read on" Appellant's original specification in a side-by-side comparison with the specification page and line number in parentheses.

Appellants' claims involved in the appeal do not include means plus function or step plus function.

The invention defined by Appellant's two independent claims 1 and 16 on appeal "consists of" a specific combination of elements that provides a microfabricated biopsy and analysis instrument that is compact, efficient, and simple to operate. The microfabricated biopsy and analysis instrument is illustrated in FIG. 2 below.

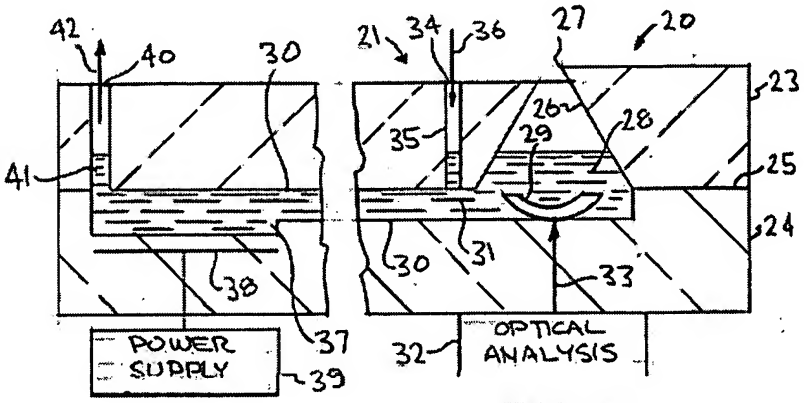

FIG. 2

The elements of Appellant's two independent claims 1 and 16 on appeal are "read on" Appellant's original specification as follows:

Claim 1	Specification & Drawings
A microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, consisting of:	The present invention involves an instrument for tissue biopsy and genetic analysis. (Page 4, lines 20-21)
a body comprising a silicon substrate and a glass substrate positioned together,	The substrate or body 13 is composed of silicon and the slot 14 and the sharp edge 16 are etched therein as described above. The substrate 13 or body 13 is bonded to a glass substrate ..... (Page 6, lines 10-12)
a cutter having a tapered opening with a sharp edge for cutting the tissue, said cutter located in said silicon substrate,	The cutter 10 is composed of a silicon substrate or body 13 having a tapered opening or slot 14 with a tapered trailing edge 15 which is located adjacent to a sharp leading edge 16 of tapered slot 14. (Page 6, lines 6-9)
a specimen chamber located in said silicon substrate and said glass substrate immediately below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter	The cutter section 20 is constructed as described in Figure 1 with a tapered opening or slot 26 having a sharp edge 27 and forming with microchannel section 21 a specimen collection chamber or pit 28, in which is located a cut tissue sample or specimen 29. (Page 6, lines 19-22)

Claim 1 (Continued)	Specification & Drawings
a specimen treatment and analysis chamber located in said silicon substrate and said glass substrate abutting and connected directly to said specimen chamber and located adjacent said specimen chamber,	The specimen treatment microchannel section 21 includes any desired number of channels 30 formed in glass substrate 24, only one being shown, and which contains a chemical solution 31 for treatment of the tissue specimen or sample 29. (Page 6, lines 23-26)
a PCR reaction chamber located in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber constructed to receive the tissue from said specimen treatment and analysis chamber, and	The PCR reaction chamber section 22 is formed in glass member or substrate 24 and includes a reaction chamber 37 connected to receive sample via microchannel 30. (Page 7, lines 6-8)
a heating unit in said body adjacent said PCR reaction chamber.	The PCR section 22 includes a heater 38 controlled and powered by a power supply 39, (Page 7, lines 8-9)

Claim 16	Specification & Drawings
A microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, consisting of:	The present invention involves an instrument for tissue biopsy and genetic analysis. (Page 4, lines 20-21)
a body comprising a silicon substrate and a glass substrate positioned together,	The substrate or body 13 is composed of silicon and the slot 14 and the sharp edge 16 are etched therein as described above. The substrate 13 or body 13 is bonded to a glass substrate ..... (Page 6, lines 10-12)

Claim 16 (Continued)	Specification & Drawings
a cutter having a tapered opening with a sharp edge for cutting the tissue, said cutter located in said body,	The cutter 10 is composed of a silicon substrate or body 13 having a tapered opening or slot 14 with a tapered trailing edge 15 which is located adjacent to a sharp leading edge 16 of tapered slot 14. (Page 6, lines 6-9)
a specimen chamber in said silicon substrate and said glass substrate located below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter,	The cutter section 20 ..... and forming with microchannel section 21 a specimen collection chamber or pit 28, in which is located a cut tissue sample or specimen 29. (Page 6, lines 19-22)
a specimen treatment and analysis chamber in said silicon substrate and said glass substrate located adjacent and directly abutting said specimen chamber and connected directly to said specimen chamber, said specimen treatment and analysis chamber having a chemical solution channel, an optical window, and an optical detection system,	The cutter section 20 ..... and forming with microchannel section 21 a specimen collection chamber or pit 28, (Page 6, lines 19-21) Optical analysis of the sample as it moves along channel 30 is accomplished as indicated at 32 and arrow 33 by a conventionally known optical detector. .. A window/optical access for excitation light may be added to the device. (Page 6, line 26 and Page 7, lines 1-5)
a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber receiving the tissue from said specimen treatment and analysis chamber, and	The PCR reaction chamber section 22 is formed in glass member or substrate 24 and includes a reaction chamber 37 connected to receive sample via microchannel 30. (Page 7, lines 6-8)

Claim 16 (Continued)	Specification & Drawings
a heating unit in said body adjacent said PCR reaction chamber.	The PCR section 22 includes a heater 38 controlled and powered by a power supply 39, (Page 7, lines 8-9)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The Final Rejection mailed March 6, 2006 states one grounds of rejection. The grounds of rejection is summarized as follows:

Grounds of Rejection - Claims 1-5 and 16-19 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the Krulevitch et al primary references (U.S. Patent No. 5,985,217 or U.S. Patent No. 6,319,474) in view of the Pourahmadi et al secondary reference (WO Patent No. 99/33559).

The grounds of rejection is stated in numbered paragraph 4, on page 2, of the Final Rejection mailed March 6, 2006.

VII. ARGUMENT

Appellants argue that claims 1-5 and 16-19 on appeal are patentable.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) include "Ascertaining the differences between the prior art and the claims at issue."

The differences between the Krulevitch et al primary references and Appellants' invention defined by claims 1-5 and 16-19 on appeal includes the fact that the Krulevitch et al primary references fail to show the following elements of Appellants' claims:

(1) Appellants' claim element: "a PCR reaction chamber," and/or

(2) Appellants' claim element: "a heating unit," and/or

(3) Appellants' claim element: "a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber," and/or

(4) Appellants' claim element: "a heating unit in said body adjacent said PCR reaction chamber," and/or

(5) Appellants' claim element: "a microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, "consisting of:" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal."

The Krulevitch et al Primary References

The Krulevitch et al primary references do not show the elements of Appellants' claims (1) through (5) listed above. Note that the Krulevitch et al primary references are completely devoid of any mention of Appellants' claim element (1) "a PCR reaction chamber" and Appellants' claim element (2) "a heating unit."

Since the Krulevitch et al primary references are completely devoid of any mention of a PCR reaction chamber and a heating unit; they also are completely devoid of any mention of Appellants' claim elements (3) "a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber" and (4) "a heating unit in said body adjacent said PCR reaction chamber."

There in nothing in the Krulevitch et al primary references to suggest "a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis

chamber," and/or "a heating unit in said body adjacent said PCR reaction chamber," and/or "an apparatus "consisting of" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal.

The Krulevitch et al primary references are also completely devoid of Appellants' claim element (5) a microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, consisting of: "the specific combinations of elements" enumerated in Appellants' claims 1-5 and 16-19 on appeal."

"Consisting of" Preamble

Appellants' claims 1-5 and 16-19 on appeal contain a "consisting of" preamble rather than a "comprising" preamble.

A "comprising" preamble is what is known as an open term. In effect, comprising is a shorthand way of saying "including the following elements but not excluding others." For example, a combination "comprising A + B" covers the combination A + B + C.

On the other hand, a "consisting of" preamble is a closed term. A combination "consisting of A + B" does not cover the combination A + B + C.

The invention defined by Appellants' claims 1-5 and 16-19 on appeal provides a specific combination of elements "consisting of" the specific combination of elements enumerated. This specific combination of elements is not found or suggested in the Krulevitch et al primary references or in the Pourahmadi et al secondary reference.

Suggestion or Motivation to Modify or Combine Reference Teachings

Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed

combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Since there is no suggestion or motivation in the Krulevitch et al primary references to modify the Krulevitch et al primary reference devices to include "a PCR reaction chamber" and/or "a heating unit" and/or to provide an apparatus "consisting of" the specific combinations of elements enumerated in Appellants' claims; a 35 U.S.C. § 103(a) rejection of Appellant's claims 1-5 and 16-19 on appeal is inappropriate and should be reversed.

The Pourahmadi et al secondary reference is an apparatus with a very different combination of elements from Appellants' microfabricated biopsy and analysis instrument as defined by Appellants' claims 1-5 and 16-19 on appeal. The Pourahmadi et al secondary reference fails to show a microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, "consisting of" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal. The Pourahmadi et al secondary reference fails to show "a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber," and/or "a heating unit in said body adjacent said PCR reaction chamber," and/or "wherein said specimen treatment and analysis chamber and said PCR reaction chamber are located in said silicon substrate and said glass substrate and said cutter is constructed of silicon and wherein said glass substrate is bonded to said silicon substrate," and/or "wherein said optical detection system is located to provide optical analysis of the tissue through said optical window of said specimen treatment and analysis chamber," of Appellants' claims 1-5 and 16-19 on appeal.

Since the Krulevitch et al primary references and the Pourahmadi et al secondary reference fail all to show the identified elements and combination of elements of Appellants' claims 1-5 and 16-19 on appeal, there could be no obvious combination of references that would produce Applicant's invention defined by Appellants' claims 1-5 and 16-19 on appeal and render Applicant's invention unpatentable.

The Pourahmadi et al Secondary Reference

FIG. 2 of the Pourahmadi et al secondary reference is provided below with captions added identifying individual elements of the Pourahmadi et al device and illustrating the combination of elements shown by the Pourahmadi et al secondary reference.

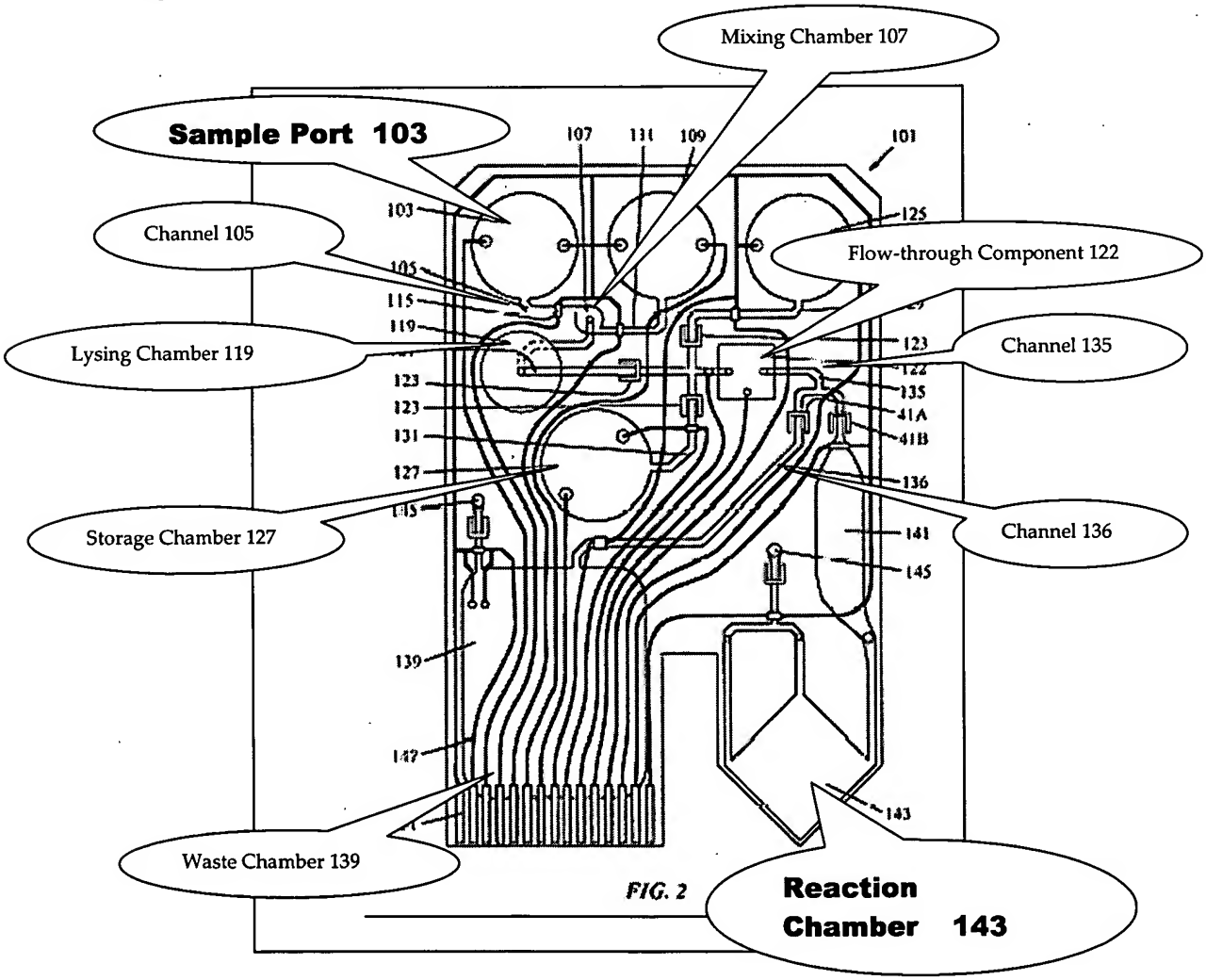

FIG. 2

The Pourahmadi et al secondary reference shows a complex device that includes numerous elements in an entirely different combination than Appellants' claimed invention "consisting of" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal. Note that in the Pourahmadi et al secondary reference device there are many intermediate elements between sample port 103 and reaction chamber 143. Some of these intermediate elements are channel 105, mixing chamber 107, lysing chamber 119, flow-through component 122, storage chamber 127, waste chamber 139, channel 135, and channel 136. Since the Pourahmadi et al secondary reference fails to show Appellants' combination of elements of Appellants' "consisting of" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal; the Pourahmadi et al secondary reference does not provide a teaching that it would be obvious to combine references to produce Applicant's claimed invention.

The Pourahmadi et al secondary reference does not show Appellants' claimed "PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber," and/or Appellants' claimed "heating unit in said body adjacent said PCR reaction chamber." Under MPEP §2142, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. It should be noted that the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

No Suggestion or Motivation to

Modify References or Combine Reference Teachings

There is no suggestion or motivation in either the Krulevitch et al primary references or in the Pourahmadi et al secondary reference to modify any of the reference devices to include any of the following claim elements of Appellants' claims 1-5 and 16-19 on appeal:

(1) a PCR reaction chamber, and/or

(2) a heating unit, and/or

(3) a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber, and/or

(4) a heating unit in said body adjacent said PCR reaction chamber, and/or

(5) "wherein" said specimen treatment and analysis chamber and said PCR reaction chamber are located in said silicon substrate and said glass substrate and said cutter is constructed of silicon and wherein said glass substrate is bonded to said silicon substrate, and/or

(6) "wherein" said optical detection system is located to provide optical analysis of the tissue through said optical window of said specimen treatment and analysis chamber, and/or

(7) a microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, "consisting of:" the specific combinations of elements enumerated in Appellants' claims 1-5 and 16-19 on appeal.

Accordingly, a 35 U.S.C. § 103(a) rejection of Appellant's claims 1-5 and 16-19 on appeal is inappropriate and should be reversed.

It is respectfully requested that Appellant's claims 1-5 and 16-19 on appeal be allowed.

Respectfully submitted,

By: 

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Telephone No. (925) 424-6897

Date: April 4, 2006

VIII. CLAIMS APPENDIX

Claim 1. A microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, consisting of:

a body comprising a silicon substrate and a glass substrate positioned together,

a cutter having a tapered opening with a sharp edge for cutting the tissue, said cutter located in said silicon substrate,

a specimen chamber located in said silicon substrate and said glass substrate immediately below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter,

a specimen treatment and analysis chamber located in said silicon substrate and said glass substrate abutting and connected directly to said specimen chamber and located adjacent said specimen chamber,

a PCR reaction chamber located in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber constructed to receive the tissue from said specimen treatment and analysis chamber, and

a heating unit in said body adjacent said PCR reaction chamber.

Claim 2. The instrument of Claim 1, wherein said sharp edge of said cutter has a smooth cutting edge with atomic sharpness capable of cutting very thin specimens of the tissue.

Claim 3. The instrument of Claim 2, wherein said cutter is constructed of silicon.

Claim 4. The instrument of Claim 1, wherein said analysis unit is an optical analysis unit.

Claim 5. The instrument of Claim 1, wherein said specimen treatment and analysis chamber and said PCR reaction chamber are located in said silicon

substrate and said glass substrate and said cutter is constructed of silicon and wherein said glass substrate is bonded to said silicon substrate.

Claim 16. A microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue, consisting of:

a body comprising a silicon substrate and a glass substrate positioned together,

a cutter having a tapered opening with a sharp edge for cutting the tissue, said cutter located in said body,

a specimen chamber in said silicon substrate and said glass substrate located below said cutter, said specimen chamber positioned to directly receive the tissue cut by said cutter,

a specimen treatment and analysis chamber in said silicon substrate and said glass substrate located adjacent and directly abutting said specimen chamber and connected directly to said specimen chamber, said specimen treatment and analysis chamber having a chemical solution channel, an optical window, and an optical detection system,

a PCR reaction chamber in said silicon substrate and said glass substrate directly abutting and connected directly to said specimen treatment and analysis chamber, said PCR reaction chamber receiving the tissue from said specimen treatment and analysis chamber, and

a heating unit in said body adjacent said PCR reaction chamber.

Claim 17. The microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue of Claim 16, wherein said PCR reaction chamber, said specimen treatment and analysis chamber, and said cutter are formed in said body.

Claim 18. The microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue of Claim 16, wherein

said sharp edge of said cutter has a smooth cutting edge with atomic sharpness capable of cutting very thin specimens of the tissue.

Claim 19. The microfabricated biopsy and analysis instrument for biopsy and analysis of tissue with minimal handling of the tissue of Claim 16, wherein said optical detection system is located to provide optical analysis of the tissue through said optical window of said specimen treatment and analysis chamber.

IX. EVIDENCE APPENDIX

There are no evidence appendix entries.

X. RELATED PROCEEDINGS APPENDIX

There are no related proceedings appendix entries.